

DEC 23 1996

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510(k) Summary of Safety and Effectiveness**PROTECTIV* 2000 IV CATHETER SAFETY SYSTEM****Company Name & Address:**

Johnson & Johnson Medical Incorporated
 2500 East Arbrook Boulevard
 Arlington, Texas 76004-3130

Identification of the Legally Marketed Device:

PROTECTIV IV Catheter Safety System and the PROTECTIV Plus IV Catheter Safety System

Description of the Device:

The PROTECTIV 2000 IV Catheter Safety System is a needle safety feature for an IV catheter. The IV catheter portion of the system is the same product that is currently marketed by JJMI. The PROTECTIV 2000 IV Catheter Safety System is designed to reduce needle stick injuries. The PROTECTIV 2000 IV Catheter Safety System is being provided on a variety of IV catheters.

Comparison Information

FEATURE	PROTECTIV I.V. AND PROTECTIV PLUS	PROTECTIV 2000
Flash back visualization	Close to catheter hub	Close to catheter hub
Locking as part of threading action	yes	yes
Tactile feel of locking	yes	yes
Audible click upon locking	yes, single click	yes, single click
Prevents needle sticks	yes	yes
Irreversible safety mechanism	yes	yes
Covered needle tip	yes	yes
Gasket wipes blood from cannula	yes	yes
One finger push to activate	yes	yes
Grips for secure handling	yes	yes
EtO sterilized	yes	yes
Single sterile wrapped	yes	yes
Designed to prevent needle sticks	yes	yes
Preloaded	yes	yes

*Trademark

Discussion of Tests/Studies with Conclusions:

The Safety system has passed all tests for safety and effectiveness (i.e. biocompatibility, sterility and system performance). The testing and conclusions are summarized below;

<i>Test</i>	<i>Conclusion</i>
Cannula Security	Passed the minimum requirement
Force to Advance/Lock	Passed the minimum requirement
IVC Safety Mechanism Efficacy	Passed the minimum requirement
Tip Protector/Primary Member Security	Passed the minimum requirement
Cannula Orientation	Passed the minimum requirement
FIPG Efficacy	Passed the minimum requirement
Biocompatibility Per ISO 10993	Passed
Simulated Clinicals	Passed
Sterilization	Passed